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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,218	01/30/2004	Yigong Shi	112911.151	9564

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EXAMINER	
KIM, ALEXANDER D	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,218	SHI, YIGONG	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-52 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, 31-42 and 47-52, drawn to a composition comprising a hetero-dimer polypeptide with caspase-9 monomer, classified in class 435, subclass 219.

II. Claims 20-25, drawn to a method of inhibiting the activity of caspase-9 and an effector caspase, classified in class 435, subclass 69.2.

III. Claims 26-30 and 46 drawn to a method of making procaspase-9 zymogen and caspase-9 polypeptide homologue, classified in class 530, subclass 350.

IV. Claims 43-45, drawn to an isolated nucleic acid molecule 90% identical to nucleic acid encoding caspase-9 F404D, caspase-9 ΔS or caspase-9 ΔL, a vector and a host of said nucleic acid molecule, classified in class 536, subclass 23.2.

3. The inventions are distinct, each from the other because of the following reasons:

Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the hetero dimer polypeptide can be used in size exclusion liquid chromatography as standard.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. For example, the polypeptide of Group I and the polynucleotide of Group IV can be made by organic synthesis.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different

classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group IV are related because the nucleic acid of Group IV encode a protein of Group I. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the nucleic acid and the protein are related. However, they are distinct inventions because they are wholly different in structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleic acid's function is to encode a protein while a protein of Group I has a certain function, in this case, protease. Therefore, a protein of Group I is mutually exclusive and not obvious variants from a nucleic acid of Group II. Also Group I cannot be used together with Group II because they have distinct function as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group III are related because a method of Group II inhibits the protein made by the method of Group III. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Group II and Group III are mutually exclusive and not obvious variants because each method steps are distinct. The method of Group II has a step of placing polypeptides together inside the mammalian subject whereas the method of Group III has steps of growing E. coli, making a cell extract and protein purification steps. The method of Group II is used for finding an inhibitor of caspase-9 enzyme, which is made from the method of Group III thus Group II and Group III have different mode of operation and function.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group IV are related because the protein encoded by the nucleic acid of Group IV is used in methods of Group II. The related inventions are distinct if the inventions as aimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Group II and Group IV are mutually exclusive and not obvious variants because the nucleic acid of Group IV are not used in process of Group II. Because, the nucleic acid encodes a protein whereas the method of Group II is used to find inhibitor of the caspase-9, the nucleic acid of Group IV and a method of Group II have different functions.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the nucleic acid of Group IV can be used as template for sequencing reactions.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Election of Species

4. This application contains claims directed to the following patentably distinct species:

In Group I, each polypeptide is distinct species, which is identified by SEQ ID NOs:

a. Species from claims dependant on Claim 1: SEQ ID NO: 14 from Claim 2, SEQ ID NO: 15 from Claim 3, SEQ ID NO: 3 from Claim 4, SEQ ID NO: R from Claim 5, SEQ ID NO: 20 from Claim 5.

b. Species from claims dependant on Claim 13: SEQ ID NO: 3 from Claim 14, SEQ ID NO: 13 from Claim 15, SEQ ID NO: 14 from Claim 17, SEQ ID NO: 15 from Claim 18.

c. Species from claims dependant on Claim 33: SEQ ID NO: 14 from Claim

34, SEQ ID NO: 15 from Claim 35, SEQ ID NO: 3 from Claim 36, SEQ ID NO: R from Claim 37, SEQ ID NO: 20 from Claim 37.

In Group III, each method expressing a distinct polypeptide of Claim 46 is distinct species.

d. SEQ ID NO: 25, SEQ ID NO: 23, SEQ ID NO: 24.

In Group IV, each nucleic acid encoding a distinct caspase-9 variant is distinct species, which is identified by SEQ ID NOs:

e. SEQ ID NO: 25, SEQ ID NO: 23, SEQ ID NO: 24.

These species are related to a polypeptide forming a hetero-dimer with a caspase-9 monomer (Group I), caspase-9 polypeptide homologues (Group III) and nucleic acids encoding caspase-9 polypeptide homologues (Group IV). However, the related species are distinct because they do not overlap in scope and are not obvious variants. For example, each species within the Group has distinct chemical structure consist of distinct amino acid or nucleic acid that is identified by SEQ ID NOs. Therefore, species of Group I, III and IV are distinct evidenced by a distinct chemical composition, a distinct structures of the claimed inventions. In addition to their distinctness, the search of each sequence requires separate sequence search, thus searching species within a Group together would impose a serious search burden on the examination process.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution from the elected Group on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group I is elected from the restriction, elect one species from a, elect one species from b and elect one species from c. Currently, Claims 1, 6-12, 13, 16, 19, 31-33, 28-42, 47-52 of the Group I is a generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
May 22, 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER